# FACT SHEET

# DIRECT FINAL AMENDMENTS TO THE NATIONAL EMISSION STANDARDS TO CONTROL HAZARDOUS AIR POLLUTANT EMISSIONS FOR FACILITIES THAT MANUFACTURE PHARMACEUTICALS

## ACTION

- On May 6, 2005, the Environmental Protection Agency (EPA) amended its National Emission Standards for Hazardous Air Pollutants for industrial facilities that manufacture pharmaceuticals.

- This amendment includes provisions for planned routine maintenance of wastewater tanks; includes alternative monitoring for condensers and scrubbers; and references general standards for wastewater containers.

- Because EPA views this action as noncontroversial, the Agency is issuing this rule as a direct final rule with a parallel proposal. If EPA receives adverse comment on the parallel proposal,we will withdraw the direct final rule and respond to the comment in an final rule amendment.

- These amendments do not alter the stringency of the September 1998 standards and have no adverse health or environmental impacts.

## BACKGROUND

- EPA issued its final air toxics rule for pharmaceutical production in September 1998. That rule required the application of maximum achievable control technology (MACT), for approximately 100 facilities manufacturing pharmaceutical products.

- Pharmaceuticals manufacturing operations covered by the rule include chemical synthesis, formulation, fermentation and extraction processes. The major air toxics to be controlled include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen. The other pollutants can cause serious health problems other than cancer in humans.

## FOR FURTHER INFORMATION . . .

- For further information about the final rule amendments, contact Randy Mcdonald of EPA's Office of Air Quality Planning and Standards at (919) 541-5402. The final rule amendments can be accessed from the Clean Air Act Amendments bulletin board of EPA's Technology Transfer Network (TTN) at the following Internet address: http://www.epa.gov/ttn/caaa/t3pfpr.html.